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March 7, 2011

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The Honorable Mitchell S. Goldberg
United States District Court for the Eastern District of Pennsylvania
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FILED

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Re: *Apotex, Inc. v. Cephalon, Inc., et al.*, C. A. No. 2:06-cv-2768

MICHAEL E. KUNZ, Clerk
By _____ Dep. Clerk

Dear Judge Goldberg:

We represent Cephalon in the above-referenced action. We write in response to the Court's invitation, made during the March 3, 2011 pre-trial conference, to submit a letter on the question of whether issues relating to the validity and enforceability of the patent-in-suit should be bifurcated and tried in advance of any issues relating to Apotex's infringement of the patent.

Cephalon objects to bifurcation. The most efficient and expeditious manner in which to resolve this case is to adjudicate all of the parties' patent claims and defenses at the March 29, 2011 trial, such that full and complete relief can be had in a single proceeding, in accordance with usual practice in these matters and the expectations of the parties. The parties have complied with the expedited schedule set by this Court, and Cephalon and its witnesses are prepared to proceed with an integrated patent trial on all issues. Leaving the infringement issues out of the trial would result in minimal savings in terms of trial time in the short run, but would add an additional layer of inefficiency, uncertainty, and possible delay down the road, both in this court and in any appeal to the Federal Circuit, in what is otherwise a relatively straightforward case.

Bifurcation in patent cases is "the exception rather than the rule." See *Innovative Office Prods., Inc. v. Spaceco, Inc.*, No. 05-4037, 2006 WL 1340865, at *1 (E.D. Pa. May 15, 2006). The Federal Circuit has expressly criticized handling patent litigation in a piecemeal fashion, suggesting that the interest of efficient judicial administration is best served when all of the issues presented are resolved in a single proceeding. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1481 (Fed. Cir. 1998). Bifurcation and piecemeal litigation in this case runs contrary to "the useful general rule that trial courts should decide all litigated issues, in the interest of finality." *Id.*; Federal Judicial Center, *Patent Case Management Judicial Guide* ("Patent Case Management Guide") 8-9 (2009) (available at [http://www.fjc.gov/public/pdf.nsf/lookup/patent01.pdf/\\$file/patent01.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/patent01.pdf/$file/patent01.pdf)) ("It is generally more efficient to have one trial and one appeal.").

Courts routinely require that all issues presented for trial in the patent portion of the case be tried in a single proceeding, even in jury cases. Indeed, non-bifurcated jury trials often cover not only the issues of infringement, validity and unenforceability, but other issues not present here, such

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as willful infringement and damages. They also often involve multiple patents and multiple products.¹

In contrast, this is a one-patent, one-product, one-defendant case, which would rarely be bifurcated, even before a jury. *See, e.g., Sprinturf, Inc. v. Southwest Recreational Indus., Inc.*, No. Civ. A. 01-7158, 2004 WL 96751, at *2 (E.D. Pa. Jan. 15, 2004) (denying request to bifurcate because the case involved “one patent, one claim and one allegedly infringing product,” and the damages issues were not complicated). “In a one-patent, one-defendant case, the overall balance of interests usually will not favor bifurcating the jury’s determination of infringement from its determination of patent validity.” *Patent Case Management Guide*, 8-9. Moreover, where the matter is a bench trial, as in this case, the issues of infringement, validity, and enforceability are almost always adjudicated in one proceeding,² because the most common concern that leads courts to consider bifurcation—the avoidance of confusion and unfair prejudice before the jury—is not applicable.³

The Court should reject bifurcation for the further reason that the time required to address the parties’ infringement disputes during the March 29, 2011 trial will be short. Cephalon estimates that it can fully present its case on infringement in two trial days. In short, Cephalon and its witnesses are (and Apotex should be) ready to proceed with trial on infringement, which, by all indications, will be an efficient and narrowly-focused matter.

Furthermore, although the Court appeared to believe that bifurcation might allow the Court to prioritize and decide the more difficult issues first, there is substantial overlap in the factual issues relating to the parties’ disputes over patent validity, enforceability, and infringement. For example:

- One of Apotex’s principal arguments in this case is that one of ordinary skill in the art would not be capable of isolating and measuring the sizes of modafinil particles after they have been formulated into a tablet, which underlies both Apotex’s contention that

¹ *See, e.g., Innovative Office Prods.*, 2006 WL 1340865, at *1 (no bifurcation in jury trial involving six patents); *Masimo Corp. v. Philips Elec. N. Am. Corp.*, No. 09-80, 2010 WL 3909969, at *2 (D. Del. Oct. 6, 2010) (no bifurcation in jury trial involving 14 patents, where court had already severed antitrust and patent misuse claims).

² *See, e.g., Novozymes A/S v. Genencor Intern., Inc.*, 474 F. Supp. 2d 592, 594 (D. Del. 2007); *Purdue Pharma, L.P. v. F.H. Faulding and Co.*, 48 F. Supp. 2d 420, 423-24 (D. Del. 1999); *National Research and Dev. Corp. v. Varian Assoc.*, 883 F. Supp. 976, 978 (D.N.J. 1995); *NEC Corp. v. Hyundai Elec. Indus.*, 30 F. Supp. 2d 546, 559 (E.D. Va. 1998); *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536, 541 (D. Del. 1998); *Magnivision, Inc. v. Opti-Ray, Inc.*, Nos. CV-91-1770, 1995 WL 151778, at *1 (E.D.N.Y. March 30, 1995).

³ *See, e.g., Keyes Fibre Co. v. Packaging Corp.*, 763 F. Supp. 374, 376 (N.D. Ill. 1991) (discussing difference between bench and jury trials for purposes of bifurcation analysis); *Eighth Floor Promotions, LLC v. R.S. Owens & Co., Inc.*, No. 2:09-CV-102, 2009 WL 2982873, at *2 (S.D. Ohio 2009) (same).

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the '516 patent is invalid under 35 U.S.C. § 112, and Apotex's challenge to Cephalon's proof of infringement.

- Another key dispute is over whether the "early lots" described in the specification of the '516 patent are prior art and/or whether one or more those lots fall within the scope of the claims, which is relevant both to Apotex's claims of invalidity and Cephalon's claim of infringement under the doctrine of equivalents.
- The dispute of the parties' infringement experts concerning the proper use of sample preparation techniques, such as sonication, to disperse modafinil particles before measuring their particle size is also at the heart of the parties' dispute over the propriety of considering the post-sonicated particle size of one of the early lots for purposes of analyzing the validity and enforceability of the '516 patent.

Finally, Apotex has the heavy burden of proving, by clear and convincing evidence, that the '516 patent is invalid or unenforceable. If Apotex fails to meet that burden, as Cephalon believes will be the case, both the Court and the parties would expend additional resources unnecessarily on reconvening for a second trial on the issue of infringement.⁴ Given the limited time required to address the parties' infringement disputes and the overlapping facts underlying the issues of validity, enforceability and infringement, a single trial would lessen the delay, expense and inconvenience to the Court and the parties.

Respectfully submitted,



Robert J. Gunther, Jr.
cc: Counsel of record

⁴ See, e.g., *WebXchange Inc. v. Dell Inc.*, No. 08-132, 2009 WL 5173485 (D. Del. Dec. 20, 2009) (denying motion to bifurcate in part due to higher burden of proof on unenforceability defense); *Cornell University v. Hewlett-Packard Co.*, No. 01-CV-1974, 2006 WL 2739678, at *6 (N.D.N.Y. Sept. 25, 2006) (same); see also *Edge Capture L.L.C. v. Lehman Bros. Holdings, Inc.*, No. 08 C 2412, 2008 WL 4083146, at *2 (N.D. Ill. 2008) (denying request to bifurcate invalidity and unenforceability from infringement because it not clear which "side is more likely to prevail on the issues of validity and enforcement").